

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India
AUTHORS	Mitra, Biswadev; Mathew, Joseph; Gupta, Amit; Cameron, Peter; O'Reilly, Gerard; Soni, Kapil; Kaushik, Gaurav; Howard, Teresa; Fahey, Madonna; Stephenson, Michael; Kumar, Vineet; Vyas, Sharad; Dharap, Satish; Patel, Pankaj; Thakor, Advait; Sharma, Naveen; Walker, Tony; Misra, Mahesh; Gruen, Russell; Fitzgerald, Mark

VERSION 1 - REVIEW

REVIEWER	Oddvar Uleberg Consultant - Anaesthesia and Critical care Department of Emergency Medicine and Pre-hospital Services St. Olav's University Hospital, Trondheim Norway
REVIEW RETURNED	26-Sep-2016

GENERAL COMMENTS	<p>Thank you for the opportunity to review the manuscript by Mitra et al – <i>"Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India"</i> (bmjopen-2016-014073). The manuscript presents several interesting questions which deserves a well-founded and structured approach. Intentions of the authors are honorable, but the journey on which they embark is formidable. In my opinion this leads to some major issues regarding both the structure and the potential feasibility of the study. Below are my remarks and questions which hopefully will help to clarify to some of these issues.</p> <p>My main concern is that there is a discrepancy throughout the manuscript regarding which main aim(s) is (are) to be investigated. This again causes some structural deficiencies in the methods section. I would expect from a protocol to have a clearly defined aim, clearly defined outcomes to be measured and much defined variables both being collected and international categorizations being used (e.g ISS / NISS).</p> <p>When reading the manuscript I find that the authors throughout the text wander between the following aims:</p> <ol style="list-style-type: none">1. Describe current status of pre-hospital notification2. Describe current trauma population
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	<p>3. Describe/examine the feasibility of a new mobile notification and triage tool</p> <p>4. Describe/examine the precision of a new mobile notification and triage tool</p> <p>5. Describe the effects of implementation of a new trauma registry</p> <p>6. And in the conclusion there is a described aim to explore current practice</p> <p>All these above mentioned aims are all important factors which are interesting, dependent of each other and should be subsequently studied. In this protocol, parts of all the above mentioned “projects” are partially described, which for me as a reader leads to a feeling of: What is the authors primary aim? After reading the protocol several times, I do feel that the author’s intention is mainly to focus on the feasibility an implementation of this new mobile notification tool – feasibility and precision. Therefore I think the authors should focus on this single topic, even though the others are all interesting. Therefore I would advise the authors to divide their aims into several projects and focusing on fewer when re-submitting this re-written manuscript. In this protocol I would as already mentioned want a more clearly defined study protocol (aim, outcome measures) regarding the implementation of a new mobile tool. Due to the above mentioned factors the current protocol does not provide the wanted detailed niveau of study design and variables to be examined. I find the clinical setting mostly well described.</p> <p>Other comments</p> <ul style="list-style-type: none"> - Page 2/14: In the abstract the authors write: “In the pre-intervention phase, prospective data on patients will be collected on pre-hospital assessment, notification, in-hospital assessment, management and outcomes and recorded in a new tailored multi-hospital registry”. This implies that there will be no pre-hospital interventions? Please clarify. - Page 4/14: In setting: The number of injured patients (N=4000) seem rather low, considering the population investigated is situated in one of the most populated areas in the world. Do you mean 4000 severely injured patients as defined by ISS > 15. Please inform / re-phrase. - In the protocol no mentioning of the time frame is described. Please clarify. - Can the authors please clarify why they state the suggested variables to be measured measured in table 1 as potential confounders as the form the basis of the new interventional tool. If I have misunderstood the intentions, please ellborate and clarify - Page 6/14: Regarding variables to be measured (decribed as potential confounders?), I would suggest the authors to describe in more detail the variables to be measured. When stating vital signs, when and by whom are they to be
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	<p>measured (pre-hospital or in-hospital, the lowest value or the first value). In order to provide some guidance I would suggest for further reading a common reporting scheme for trauma: Ringdal et al. The Utstein template for uniform reporting of data following major trauma: A joint revision by SCANTEM, TARN, DGU-TR and RITG. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2008, 16:7. This would allow for a pre-defined variable set, less prone to post-interventional individual interpretations</p> <ul style="list-style-type: none"> - When implementing a new electronic device (electronic patient chart) transferring sensitive patient data, it would seem compulsory to describe any efforts taken regarding to secure these data. <p>Conclusion</p> <p>I find that the manuscript has potential to describe a most interesting project, though the authors need to narrow their aim and provide a more detailed description on how to investigate and evaluate this specific aim. I would be happy to review a re-written manuscript.</p>
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REVIEWER	Joel Stitzel Wake Forest University, USA
REVIEW RETURNED	29-Dec-2016

GENERAL COMMENTS	<p>Review: Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India</p> <p>The authors are presenting a protocol for the evaluation of a formalized approach to prehospital notification.</p> <p>The scope is large and the potential impact is great. The public health importance of this to India is paramount.</p> <p>The manuscript does need some English language editing.</p> <p>The golden rule to see a patient within an hour, and also the 'right person, right place, right time' mantra may be helpful to discuss and implement as background. Also it maybe good to cite sentinel papers like MacKenzie discussing improved mortality of those treated at a trauma center. (Never mind the MacKenzie paper is in there!)</p> <p>I found it fascinating to learn how patients are transported by police vs ambulance in a place like Delhi. I think it would be good to give a better citation for the report or perhaps to at least reference the personal communication or report title even if not peer reviewed journal.</p> <p>Please provide information about the percentage of the population being studied to augment your numbers of people and the population and area and population density of rural and urban areas surrounding the four major trauma centers. Also, estimates of the</p>
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	<p>percentage of badly injured patients currently going to other referring or community / local hospitals versus these major trauma centers.</p> <p>Also, how does one define a 'major trauma centre' in India? Is there a certification or other way this is done? Please report this in the manuscript.</p> <p>How were the existing priority categories determined? Please report this (red vs yellow). (Never mind I've found this in the manuscript)</p> <p>How will data collectors be ensured and how is trauma registry data entered and by whom? What is the protocol for ensuring this will work? Who provides the funding? What is the inclusion agreement for the hospitals and is there an agreement in place that assures it will pass to the next administration or executive as leadership changes? Funding – I found this thank you. What is the total amount of funding required or awarded if available?</p> <p>If so many people arrive by police car, why limit to only those arriving by ambulance? It seems this would be an important piece of information for subsequent study and intervention. It may be very closely related to proximity to the TC which is important.</p> <p>How will one discriminate from Dead at scene, which is excluded, and dead on arrival, which is included? Would presumably one dead at scene not be transported to hospital?</p> <p>Why exclude single digit finger or to amputations, as these are injuries also? Which may be included with other injuries including AIS 1 injuries and require hospitalization.</p> <p>What is the android application? If it exists is it to be developed, or it has a name now? Do people use iphones, will the devices be also provided to the individuals who use them in the field?</p> <p>Please report the AIS version to be used and cite the report (aaam.org has information).</p> <p>For Discussion please report the rates of Years productive life lost if those are available for injury.</p> <p>What will be done with ICD 9 or ICD 10 coding, and also with CPT codes, if these are used? These data would be valuable to have. Particularly ICD in addition to AIS. Also there is a mechanism code for ICD 9 and 10, for 10 it is the V,W,X,and Y codes in Chapter 20. I think this data should be collected and would be tremendously valuable to code. I recommend it is added if it is not included.</p> <p>Thanks for an ambitious study which I would like to see come to fruition for the sake of care of the injured in India.</p>
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VERSION 1 – AUTHOR RESPONSE

My main concern is that there is a discrepancy throughout the manuscript regarding which main aim(s) is (are) to be investigated. This again causes some structural deficiencies in the methods section. I would expect from a protocol to have a clearly defined aim, clearly defined outcomes to be measured and much defined variables both being collected and international categorizations being used (e.g ISS / NISS).

When reading the manuscript I find that the authors throughout the text wander between the following aims:

1. Describe current status of pre-hospital notification
2. Describe current trauma population
3. Describe/examine the feasibility of a new mobile notification and triage tool
4. Describe/examine the precision of a new mobile notification and triage tool
5. Describe the effects of implementation of a new trauma registry
6. And in the conclusion there is a described aim to explore current practice

All these above mentioned aims are all important factors which are interesting, dependent of each other and should be subsequently studied. In this protocol, parts of all the above mentioned "projects" are partially described, which for me as a reader leads to a feeling of: What is the authors primary aim? After reading the protocol several times, I do feel that the author's intention is mainly to focus on the feasibility an implementation of this new mobile notification tool – feasibility and precision. Therefore I think the authors should focus on this single topic, even though the others are all interesting. Therefore I would advise the authors to divide their aims into several projects and focusing on fewer when re-submitting this re-written manuscript. In this protocol I would as already mentioned want a more clearly defined study protocol (aim, outcome measures) regarding the implementation of a new mobile tool. Due to the above mentioned factors the current protocol does not provide the wanted detailed niveau of study design and variables to be examined. I find the clinical setting mostly well described.

- We agree with the reviewer's comments. We have streamlined the aim to only state the primary aim only. Aims revised to:

The primary aim of this project is to evaluate the effectiveness of a protocolised pre-hospital notification system using existent smartphones to improve the rate of pre-hospital notification of injured patients arriving to major trauma centres.

The study design and discussion have been further amended to focus on this aim

Other comments

Page 2/14: In the abstract the authors write: "In the pre-intervention phase, prospective data on patients will be collected on pre-hospital assessment, notification, in-hospital assessment, management and outcomes and recorded in a new tailored multi-hospital registry". This implies that there will be no pre-hospital interventions? Please clarify.

- There will be no pre-hospital intervention in the pre-intervention phase. This phase is for prospective data collection of current practice.

Page 4/14: In setting: The number of injured patients (N=4000) seem rather low, considering the population investigated is situated in one of the most populated areas in the world. Do you mean 4000 severely injured patients as defined by ISS > 15. Please inform / re-phrase.

- Paragraph revised to qualify severity of injured patients where available. All sites do not currently report this data using ISS.

In the protocol no mentioning of the time frame is described. Please clarify.

- Timelines added to Page 10:

Pre-intervention data collection commenced in May 2016. The intervention will commence in February 2017, with expected completion of the project by May 2017.

Can the authors please clarify why they state the suggested variables to be measured measured in table 1 as potential confounders as the form the basis of the new interventional tool. If I have misunderstood the intentions, please ellborate and clarify

- The term “potential confounders” deleted and replaced with ‘Exposure variables”

Page 6/14: Regarding variables to be measured (decribed as potential confounders?), I would suggest the authors to describe in more detail the variables to be measured. When stating vital signs, when and by whom are they to be measured (pre-hospital or in-hospital, the lowest value or the first value). In order to provide some guidance I would suggest for further reading a common reporting scheme for trauma: Ringdal et al. The Utstein template for uniform reporting of data following major trauma: A joint revision by SCANTEM, TARN, DGUTR and RITG. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2008, 16:7. This would allow for a pre-defined variable set, less prone to post-interventional individual interpretations

- We agree the Utstein Template would be an ideal tool to report on major trauma epidemiology and outcomes. However, we appreciate accurate and sustained data collection at that this level of detail will not be possible in our setting. Variable training levels of pre-hospital staff further limits pre-hospital data collection. Hence, data collection points were simplified to cater for the population being studied.

When implementing a new electronic device (electronic patient chart) transferring sensitive patient data, it would seem compulsory to describe any efforts taken regarding to secure these data.

- Information on encryption of data now added:

The Suchana application will be accessed by emergency medical technician via a unique login and device registration. No identifying information is collected by the application with an incident identification number linking the application data to the AITSC Trauma Registry, which is hosted on a secure hospital server in Delhi. The network traffic between the application and the hospital server is Secure Sockets Layer (SSL) encrypted with HTTPS based protocols.

The authors are presenting a protocol for the evaluation of a formalized approach to prehospital notification.

The scope is large and the potential impact is great. The public health importance of this to India is paramount.

The manuscript does need some English language editing.

The golden rule to see a patient within an hour, and also the ‘right person, right place, right time’ mantra may be helpful to discuss and implement as background. Also it maybe good to cite sentinel papers like MacKenzie discussing improved mortality of those treated at a trauma center. (Never mind the MacKenzie paper is in there!)

- Thank you.

I found it fascinating to learn how patients are transported by police vs ambulance in a place like Delhi. I think it would be good to give a better citation for the report or perhaps to at least reference the personal communication or report title even if not peer reviewed journal.

- Reference added: Gupta Amit, Misra Mahesh C, Kumar Subodh, Sagar Sushma, Mishra Biplab, Singhal, Maneesh, Bhoi Sanjeev, K, Jhakar Ashish. Hospital Injury Surveillance and Trauma Registry Report 2011-2012. JPNATC, AIIMS, New Delhi Publication 2013. ISBN: 978-93-5126-263-3.

Also, how does one define a ‘major trauma centre’ in India? Is there a certification or other way this is done? Please report this in the manuscript.

- Added to manuscript: In India, any teaching hospital serviced by specialty departments of general surgery, orthopaedics and neurosurgery are considered to be major trauma centres.

How were the existing priority categories determined? Please report this (red vs yellow). (Never mind I've found this in the manuscript)

- Thank you

How will data collectors be ensured and how is trauma registry data entered and by whom? What is the protocol for ensuring this will work?

- We have streamlined the aims of this manuscript for the pre-hospital intervention only and hence refrained from describing the trauma registry in detail. We expect this will be described in a subsequent manuscript. Dedicated staff are being trained to enter data and maintain the registry along with a trauma quality improvement program.

Who provides the funding? What is the inclusion agreement for the hospitals and is there an agreement in place that assures it will pass to the next administration or executive as leadership changes? Funding – I found this thank you. What is the total amount of funding required or awarded if available?

- Thank you. The total funding for the entire project is AUD2,600,500 and covers:

Trauma Registry Development

Pre-Hospital Notification

Trauma Reception and Resuscitation (TRR©) System

Trauma Quality Improvement

Rehabilitation After Discharge

Details are available at: <http://aitsc.org/programs/>

If so many people arrive by police car, why limit to only those arriving by ambulance? It seems this would be an important piece of information for subsequent study and intervention. It may be very closely related to proximity to the TC which is important.

- The primary intervention of triage through the use of mechanism, injuries and vital signs require some medical training. We accept that such basic training is indicated among all first responders (as is the case in advanced trauma systems), but beyond the scope of this study.

In addition, pre-hospital services are rapidly expanding across India with over 20 states with some form of Government or Private-Public Partnership pre-hospital/emergency service. India is rapidly moving toward a Western model of pre-hospital service with the aim that all major traumas will arrive by BLS or ALS ambulance. Our project is directed toward the ambulance services – other groups such as the SaveLIFE Foundation, an independent, non-profit, non-governmental organization focused on improving road safety and emergency medical care across India, who have introduced a training program for Police as first responders. Other groups that have introduced similar programs in India are the Society of Indian Automotive Manufacturers and the International Road Federation in Geneva.

How will one discriminate from Dead at scene, which is excluded, and dead on arrival, which is included? Would presumably one dead at scene not be transported to hospital?

- Methods amended- Dead at scene = not transported to hospital

Why exclude single digit finger or to amputations, as these are injuries also? Which may be included

with other injuries including AIS 1 injuries and require hospitalization.

- For the purpose of this study, we wish to include the population that may benefit from pre-hospital notification. We do not think patients with single digit amputations will benefit from pre-hospital notification

What is the android application? If it exists is it to be developed, or it has a name now? Do people use iphones, will the devices be also provided to the individuals who use them in the field?

- The android application is being custom designed for this intervention. It is named Suchana (added to manuscript). Pre-hospital providers all have smart-phones (discovered on our scoping visits).

Please report the AIS version to be used and cite the report (aaam.org has information).

- 2005 Update 2008 (AIS 2008) will be used- added to Methods with citation.

For Discussion please report the rates of Years productive life lost if those are available for injury.

- Added to discussion:

The burden is borne disproportionately by young people with a regional report concluding a total of 6134 life years were lost each year in a population of 108 000 following unintentional injuries.

What will be done with ICD 9 or ICD 10 coding, and also with CPT codes, if these are used? These data would be valuable to have. Particularly ICD in addition to AIS. Also there is a mechanism code for ICD 9 and 10, for 10 it is the V,W,X,and Y codes in Chapter 20. I think this data should be collected and would be tremendously valuable to code. I recommend it is added if it is not included.

- ICD10 Injury Diagnosis Codes are not collected currently in the Registry.

ICD10 External Cause Codes are collected for Activity, Location and Intent. For Mechanism, ICD10 codes have been aggregated / condensed to improve feasibility / completeness / accuracy.

Thanks for an ambitious study which I would like to see come to fruition for the sake of care of the injured in India.

VERSION 2 – REVIEW

REVIEWER	Joel Stitzel Wake Forest University, United States
REVIEW RETURNED	13-Feb-2017

GENERAL COMMENTS	<p>The authors have addressed all my comments. With one or two minor exceptions I think it is ready to go. Some things were addressed in response to comments that should be included somehow in the paper.</p> <ol style="list-style-type: none">1. ICD10 External Cause Codes are collected for Activity, Location and Intent. For Mechanism, ICD10 codes have been aggregated / condensed to improve feasibility / completeness / accuracy.2. Isn't it possible that one not transported to hospital would just not have sufficient injury, or would have refused transport or care? It is still not clear methodologically.3. I'm not sure this is an answer to the original question. And, the additional text would be helpful to include in the manuscript: <p>If so many people arrive by police car, why limit to only those</p>
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	<p>arriving by ambulance? It seems this would be an important piece of information for subsequent study and intervention. It may be very closely related to proximity to the TC which is important.</p> <p>- The primary intervention of triage through the use of mechanism, injuries and vital signs require some medical training. We accept that such basic training is indicated among all first responders (as is the case in advanced trauma systems), but beyond the scope of this study. (It is not clear why this is beyond scope or how this answers the question asked)</p> <p>In addition, pre-hospital services are rapidly expanding across India with over 20 states with some form of Government or Private-Public Partnership pre-hospital/emergency service. India is rapidly moving toward a Western model of pre-hospital service with the aim that all major traumas will arrive by BLS or ALS ambulance. Our project is directed toward the ambulance services – other groups such as the SaveLIFE Foundation, an independent, non-profit, non-governmental organization focused on improving road safety and emergency medical care across India, who have introduced a training program for Police as first responders. Other groups that have introduced similar programs in India are the Society of Indian Automotive Manufacturers and the International Road Federation in Geneva.</p> <p>- Please add some of this information in the paragraph above to the manuscript, indicating how it addresses the question and if it indicates truly that India is moving toward a 100% ambulance based activity, and that therefore this is the only thing necessary to study, please say so. If badly injured people are transported to trauma centers without ambulance support, please estimate the numbers and potential implications for not including them in this study. If it is simply just that the funding is not there to evaluate prehospital transportation that is not by ambulance, please say so.</p> <p>Thanks to the authors for addressing the concerns.</p>
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VERSION 2 – AUTHOR RESPONSE

Some things were addressed in response to comments that should be included somehow in the paper.

1. ICD10 External Cause Codes are collected for Activity, Location and Intent. For Mechanism, ICD10 codes have been aggregated / condensed to improve feasibility / completeness / accuracy.

Response: This has been added to the Manuscript- Page 6

2. Isn't it possible that one not transported to hospital would just not have sufficient injury, or would have refused transport or care? It is still not clear methodologically.

Response: We agree, and such patients would be excluded from the study. Added to manuscript: Data on injured patients arriving by other means, e.g. private car or police will be included in the registry and numbers and outcomes reported, but not analysed as an outcome of the intervention, as the intervention would not be available to such patients as part of this study. (Page 5)

3. I'm not sure this is an answer to the original question. And, the additional text would be helpful to

include in the manuscript:

If so many people arrive by police car, why limit to only those arriving by ambulance? It seems this would be an important piece of information for subsequent study and intervention. It may be very closely related to proximity to the TC which is important.

- The primary intervention of triage through the use of mechanism, injuries and vital signs require some medical training. We accept that such basic training is indicated among all first responders (as is the case in advanced trauma systems), but beyond the scope of this study.
(It is not clear why this is beyond scope or how this answers the question asked)

Response: Police and other first responders would require at least basic training in medical assessment (e.g. how to measure blood pressure, heart rate, conscious state to use the device. We agree with the reviewer's opinion that this is important, but from a resource perspective, beyond the scope of this project. Added to discussion on Page 11

In addition, pre-hospital services are rapidly expanding across India with over 20 states with some form of Government or Private-Public Partnership pre-hospital/emergency service. India is rapidly moving toward a Western model of pre-hospital service with the aim that all major traumas will arrive by BLS or ALS ambulance. Our project is directed toward the ambulance services – other groups such as the SaveLIFE Foundation, an independent, non-profit, non-governmental organization focused on improving road safety and emergency medical care across India, who have introduced a training program for Police as first responders. Other groups that have introduced similar programs in India are the Society of Indian Automotive Manufacturers and the International Road Federation in Geneva.

Response: Added to discussion- Page 11

- Please add some of this information in the paragraph above to the manuscript, indicating how it addresses the question and if it indicates truly that India is moving toward a 100% ambulance based activity, and that therefore this is the only thing necessary to study, please say so. If badly injured people are transported to trauma centers without ambulance support, please estimate the numbers and potential implications for not including them in this study. If it is simply just that the funding is not there to evaluate prehospital transportation that is not by ambulance, please say so.

Response: The limitation of resources to train all pre-hospital providers added to the discussion- Page 11